

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Elan and Adam Klein, Leah Weaver, and
Arisa Paschalidis, and all others similarly
situated,

Civil Action No. _____

Plaintiffs,

CLASS ACTION COMPLAINT

v.

Prime Therapeutics, LLC; Express Scripts
Holding Co.; Express Scripts, Inc.; and
CVS Health Corp.,

Defendants.

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FIRST CLAIM FOR RELIEF

ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3) for Breach of Fiduciary Duties under ERISA

§ 404(a)(1)(A), 29 U.S.C. § 11-4(a) 50

SECOND CLAIM FOR RELIEF

ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3) for Prohibited Transactions under ERISA

§ 406(b)(2), 29 U.S.C. § 1106(b)(2) 51

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I. INTRODUCTION

1. This is an action under the Employee Retirement Income Security Act of 1974 (“ERISA”) on behalf of all persons in the United States and its territories who are participants in, or beneficiaries of, health insurance plans governed by ERISA who, pursuant to the terms of their health insurance plans, paid any portion of the purchase price for EpiPen or EpiPen Jr. (the “Class,” as defined in detail in Section V below).

2. Under ERISA, a fiduciary is required to discharge its duties with respect to an ERISA-governed health insurance plan solely in the interest of the plan’s participants and beneficiaries (collectively, “plan members”) and for the exclusive purpose of providing benefits to plan members. ERISA also prohibits fiduciaries from engaging in any transaction involving an ERISA-governed health insurance plan on behalf of a party whose interests are adverse to the interests of the plan members.

3. EpiPen and EpiPen Jr. (collectively, “EpiPen”) are devices designed to inject epinephrine into a person experiencing a severe, life-threatening allergic reaction known as anaphylaxis. Approximately 43 million people are at risk of suffering anaphylaxis, and more than 3.6 million EpiPen prescriptions were written in 2015. The price of an EpiPen two-pack has continuously increased from \$93.88 in 2007 to \$608.61 in 2016.

4. The framework of prescription drug distribution, pricing, and reimbursement in the United States has become complex and opaque. Defendants have played a significant role in the development of this framework and have exploited and profited from the resulting confusion and lack of awareness.

5. However, Plaintiffs' basic claim is simple. Defendants Prime Therapeutics, LLC; CVS Health Corp.; Express Scripts, Inc.; and Express Scripts Holding Co. are pharmacy benefit managers ("PBMs"). PBMs have fiduciary duties to members of the ERISA health insurance plans the PBMs help administer. Part of those fiduciary duties relate to the PBMs' negotiation of drug prices with pharmaceutical companies like Mylan, the company that markets and sells EpiPen. Defendant PBMs violated their fiduciary duties by causing the highly inflated prices paid by Class members for EpiPen. Indeed, instead of negotiating for lower or stable prices for all plan members, Defendants negotiated for increasingly large rebates from Mylan for themselves and their clients, driving up the price of EpiPen. Rather than passing these rebates on to Class members in the form of lower or stable prices, Defendants kept significant amounts, resulting in *massive revenue increases* for themselves and *massive price increases* for members of the Class. Defendants are liable under ERISA for this misconduct.

6. This highly profitable, rebate-seeking conduct by Defendant PBMs has inflated EpiPen prices and had an enormous impact on EpiPen spending. According to a recent analysis published by the Journal of the American Medical Association, between 2007 and 2014, total EpiPen spending increased astronomically, nearly 1,000%. Further, the conduct of Defendant PBMs has caused EpiPen deductible payments—the EpiPen price paid by Class members with annual health insurance deductibles—to increase by *nearly 1,600%*, and EpiPen coinsurance payments—the percentage of the EpiPen price paid by Class members with coinsurance—to increase by *more than 1,500%*.

7. Plaintiffs' allegations are based on their own experience and personal knowledge, their research, the research of counsel, publicly available articles, studies, reports, and other sources, a reasonable inquiry under the circumstances, and on information and belief. Plaintiffs' allegations are likely to have further evidentiary support after a reasonable opportunity for further investigation and discovery.

II. PARTIES

A. Plaintiffs

8. Plaintiffs Elan and Adam Klein ("the Kleins") are residents of Lake Worth, Florida. The Kleins have a six-year-old son who has severe allergies to eggs, dairy, nuts, and seeds. Since October 2013, the Kleins have been participants in an ERISA-governed health insurance plan. Defendant Prime provides pharmacy benefit management services to the Kleins under that plan.

9. Plaintiff Leah Weaver ("Weaver") is a resident of Minneapolis, Minnesota. Her ten-year-old daughter has a severe tree nut allergy. Beginning in 2013 through 2014, Weaver and her daughter were participants in an ERISA-governed health insurance plan for which Express Scripts provided pharmacy benefit management services. Beginning in 2015 through 2016, Weaver and her daughter were participants in an ERISA-governed health insurance plan for which CVS Health provided pharmacy benefit management services. Since approximately January 1, 2017, Weaver and her daughter have been participants in an ERISA-governed health insurance plan for which Express Scripts provides pharmacy benefit management services.

10. Plaintiff Arissa Paschalidis (“Paschalidis”) is a resident of Fort Lee, New Jersey. Paschalidis has severe allergies to tree nuts and tree pollen. From October 2013 to August 2014, Paschalidis was a participant in an ERISA-governed health insurance plan. Defendant Prime provided pharmacy benefit management services to Paschalidis under that plan.

B. Defendants

11. Defendant Prime Therapeutics, LLC (“Prime”) is a pharmacy benefit manager headquartered at 1305 Corporate Center Drive, Eagan, Minnesota 55121 and organized under Delaware law. Prime is owned by seventeen Blue Cross and Blue Shield health insurance entities. Prime provides pharmacy benefit management services to those seventeen Blue Cross and Blue Shield health insurance entities on behalf of more than 20 million plan participants.

12. Defendants Express Scripts Holding Co. and Express Scripts, Inc. (collectively, “Express Scripts”) are pharmacy benefit managers headquartered at One Express Way, St. Louis, Missouri 63121 and incorporated in Delaware. Express Scripts, Inc. is a wholly-owned subsidiary of Express Scripts Holding Corp. Express Scripts provides pharmacy benefit management services to various health insurance entities on behalf of 83 million plan participants.

13. Defendant CVS Health Corp. (“CVS Health”) is a pharmacy benefit manager headquartered at One CVS Drive, Woonsocket, Rhode Island 02895 and incorporated in Delaware. CVS Health provides pharmacy benefit management services to various health insurance entities on behalf of nearly 90 million PBM plan members.

III. JURISDICTION AND VENUE

14. The Court has federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and 29 U.S.C. § 1132(e), because Plaintiffs' claims arise under ERISA.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in the District of Minnesota, and because some of the actions giving rise to the complaint took place within this district.

16. The Court has personal jurisdiction over the Defendants. Defendant Prime is headquartered in this judicial district. Defendants Express Scripts Holding Corp., Express Scripts, Inc., and CVS Health administer the ERISA health insurance plan prescription drug benefits of many Class members in this judicial district, including administering the ERISA health insurance plan prescription drug benefits of Plaintiff Leah Weaver. Defendants Express Scripts Holding Corp., Express Scripts, Inc., and CVS Health enter into transactions with numerous clients in this district, including employers that sponsor ERISA health insurance plans and health insurers that provide ERISA health insurance plans, in which many Class members participate and that give rise to the fiduciary relationship and violations alleged herein.

IV. FACTUAL BACKGROUND

A. Prescription Drug Distribution and Reimbursement

17. Prescription drug distribution and reimbursement involves a variety of entities, including pharmaceutical companies, wholesalers, pharmacies, health insurers, and pharmacy benefit managers.

i. The Prescription Drug Distribution Chain

18. *Pharmaceutical Companies.* Pharmaceutical companies, also referred to herein as “drug companies,” own the rights to manufacture, market, and sell drugs. Pharmaceutical companies sell drugs, including EpiPen, to drug wholesalers. Mylan N.V. (“Mylan”), a pharmaceutical company, markets and sells EpiPen. Mylan acquired EpiPen from Merck KGaA in 2007.

19. *Wholesalers.* Drug wholesalers purchase bulk quantities of drugs directly from drug companies to distribute to pharmacies and hospitals. For example, a wholesaler may fill an order from a pharmacy for a specified quantity of drugs from one or more drug companies and deliver the order to the pharmacy. Three wholesalers—AmerisourceBergen Corporation, Cardinal Health Inc. and McKesson Corporation—account for over 85% of all drug distribution in the United States.

20. *Pharmacies.* Pharmacies typically purchase pharmaceuticals from wholesalers to dispense to patients. Pharmacies dispense drugs in several types of settings, including retail pharmacies, mail order, hospitals, long-term care facilities, and others.

21. In short, drugs such as EpiPen have the following chain of distribution between the drug company and the ultimate patient-consumer: (i) the drug company sells the drug to a wholesaler; (ii) the wholesaler sells the drug to a pharmacy or other drug dispensary; and (iii) the pharmacy (or other dispensary) dispenses the drug to the patient-consumer.

ii. The Prescription Drug Reimbursement Chain

22. *Health Insurers.* Health insurers offer health insurance plans, including medical and prescription drug benefits. Individuals and entities purchase health insurance plans through the payment of premiums, typically on a monthly basis.

23. Employers may sponsor a health insurance plan in one of two ways. First, an employer may purchase a health insurance plan from a health insurer, and the health insurer provides healthcare benefits (*i.e.* medical and prescription drug benefits) to employees. Second, an employer may set aside funds to directly provide healthcare benefits to employees, paying for their medical and prescription drug benefits itself. Such employers are often referred to as “self-insured.” A self-insured employer contracts with a health insurer to administer healthcare benefits on behalf of the employer’s health insurance plan.

24. *Pharmacy Benefit Managers.* The prescription drug reimbursement chain is heavily controlled by pharmacy benefit managers. In most instances, the health insurer contracts with a specific PBM to administer the plan’s prescription drug benefits.

25. For those who receive prescription drug benefits through a self-insured employer health plan, a PBM will administer the plan’s prescription drug benefits pursuant to an agreement with the plan’s health insurer, or the self-insured employer will contract directly with a specific PBM to administer the plan’s prescription drug benefits.

26. According to the Pharmaceutical Care Management Association, as of 2016, PBMs administer prescription drug benefits for 266 million Americans. The four largest PBMs—Express Scripts; CVS Health; OptumRx, Inc. (“Optum”); and Prime—

administer prescription drug benefits for more than 200 million Americans. In administering prescription drug benefits, PBMs determine (i) health plan members' eligibility for prescription drug benefits; (ii) the amount of prescription drug benefits to be paid to health plan members; and (iii) health plan members' cost-sharing obligations.

27. PBMs do not take possession or control of prescription drugs that are dispensed at retail pharmacies.¹ Rather, they act as an intermediary between the health insurers and self-insured employers with whom they contract (collectively, "Third-Party Payers") and retail pharmacies. PBMs create networks of retail pharmacies and negotiate reimbursement rates with those pharmacies for prescription drugs that are dispensed to plan members with PBM-administered prescription drug benefits. Separately, PBMs negotiate with their Third-Party Payer clients regarding reimbursement rates for prescription drugs.

28. When an individual plan member presents a prescription at a pharmacy, the pharmacy transmits the prescription information to the PBM. This is known as a prescription drug benefit claim. The PBM then sends a message back to the pharmacy indicating whether the individual is eligible for prescription drug benefits and, if so, (1) the amount the pharmacy will be reimbursed for dispensing the drug, and (2) the amount the pharmacy must collect from the individual.

29. In short, PBMs process prescription drug benefit claims and reimburse pharmacies for those claims, pursuant to a contracted rate between the PBMs and the pharmacies. Third-Party Payers then reimburse their respective PBMs for those same

¹ Certain PBMs own mail-order and specialty pharmacies that do purchase and dispense drugs to plan members.

prescription drug benefit claims, pursuant to a separately contracted rate between the PBMs and the Third-Party Payers. This reimbursement chain, as well as the previously discussed drug distribution chain, is graphically depicted below.

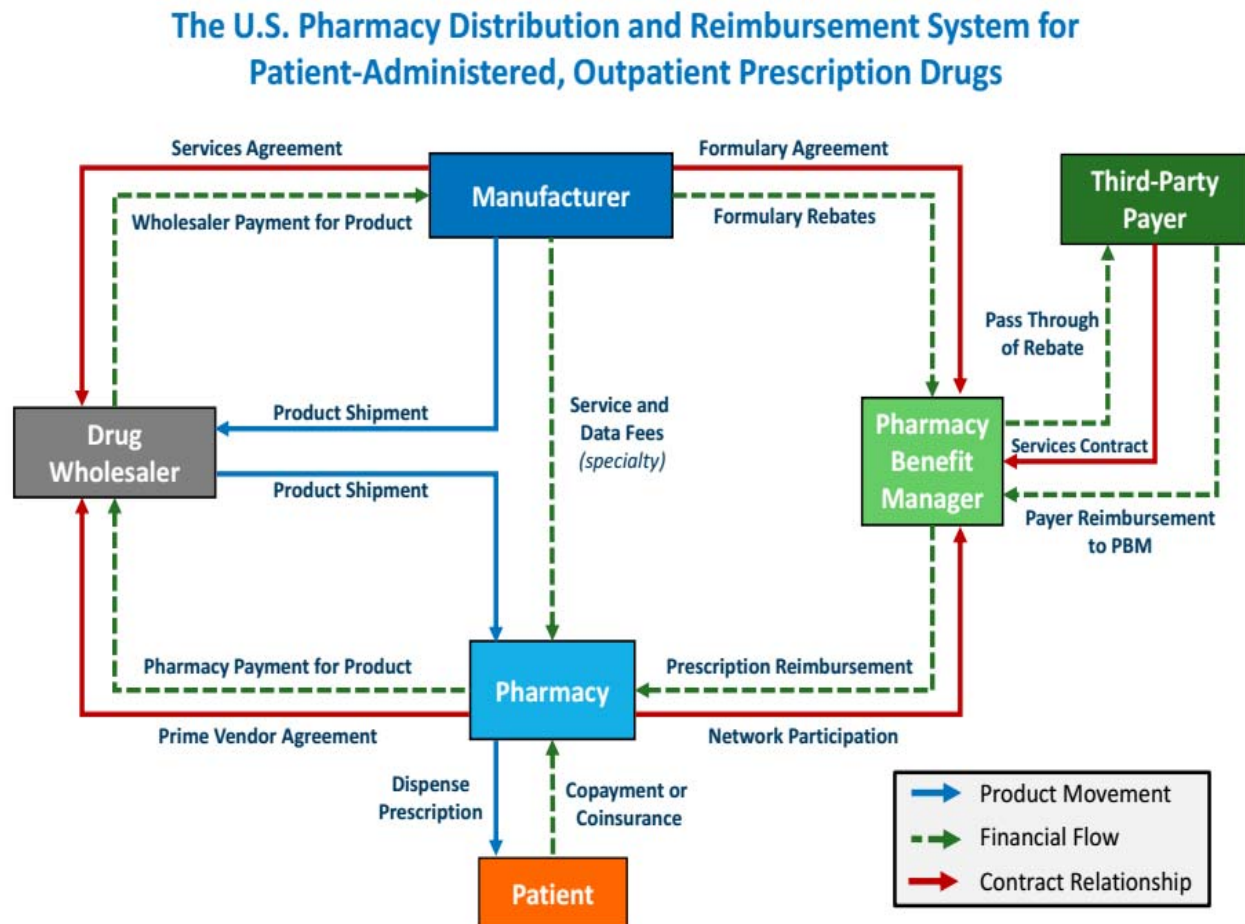


Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.

Source: Fein, Adam J., *The 2016 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2016.

(Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/)

a. Third-Party Payers and PBMs Pay Different Prices in the Reimbursement Chain

30. Given that prescription drug reimbursements are determined by one contract between pharmacies and PBMs, and a separate contract between PBMs and Third-Party Payers, PBMs often reimburse pharmacies for lesser amounts than what

Third-Party Payers reimburse PBMs. The difference between what PBMs reimburse pharmacies and what Third-Party Payers reimburse PBMs is known as the “spread.” The spread is kept by PBMs as a substantial source of profit.

31. The amounts that PBMs reimburse pharmacies, and the amounts that Third-Party Payers reimburse PBMs, are kept secret. Only a drug’s Average Wholesale Price (“AWP”) is publicly reported. AWP is a benchmark price that is published in pharmaceutical price indexes. A related benchmark price, Wholesale Acquisition Cost (“WAC”), is the price at which drug companies sell brand name drugs like EpiPen to wholesalers. A given drug’s AWP is based on its WAC plus an average markup of 20%.

32. In general, AWP or WAC is the starting point in determining reimbursement rates for brand name drugs, including EpiPen. For a given brand name drug, like EpiPen, pharmacies are generally reimbursed an amount between the drug’s AWP and WAC. For example, a PBM might reimburse a pharmacy for brand name drugs at AWP minus 15%, while the Third-Party Payer might reimburse the PBM for brand name drugs at AWP minus 12%. The PBM will keep the 3% spread as profit. If these reimbursements were instead based on WAC, the PBM would reimburse the pharmacy at WAC plus 6.25%, the Third-Party Payer would reimburse the PBM at WAC plus 10%, and the PBM would keep the 3.75% spread as profit.

33. By way of further example, for a drug with a WAC of \$300 and an AWP of \$360, under AWP, the PBM might reimburse the pharmacy \$306, the Third-Party Payer might reimburse the PBM \$316.80, and the PBM would keep \$10.80. Under WAC, a PBM might reimburse the pharmacy \$318.75, the Third-Party Payer might reimburse the

PBM \$330, and the PBM would keep \$11.25.

Figure 1 AWP to WAC Conversion Chart²

Converting from an AWP discount to a WAC based discount*

AWP Discount	WAC Plus Equivalent
12.00%	10.00%
12.50%	9.38%
13.00%	8.75%
13.50%	8.13%
14.00%	7.50%
14.50%	6.88%
15.00%	6.25%
15.50%	5.62%
16.00%	5.00%
16.50%	4.38%
17.00%	3.75%
17.50%	3.13%
18.00%	2.50%
18.50%	1.88%
19.00%	1.25%
19.50%	0.63%
20.00%	0.00%

*The conversion chart is compliments of Pharmacy Providers of Oklahoma (PPOk).
<http://www.ppok.com/>

² Available at <https://www.ncpanet.org/pdf/fdbinfosheet.pdf>.

B. PBM Rebates and Formularies

34. In addition to serving as an intermediary between Third-Party Payers and pharmacies in the prescription drug reimbursement chain, PBMs serve as an intermediary between drug companies, including Mylan, and Third-Party Payers. Specifically, PBMs solicit discounts from drug companies off of the AWP or WAC of brand name drugs in exchange for placement on “*formularies*”—lists of drugs for which PBMs’ Third-Party Payer clients provide prescription drug benefits to plan members.

35. Drug company discounts come in the form of rebates paid to PBMs. Rebates are paid pursuant to one or more rebate agreements between the drug company and the PBM.

36. Rebates paid in exchange for formulary placement are commonly known as “access rebates.” In general, access rebates are retained exclusively by PBMs, rather than passed on to Third-Party Payers, and therefore constitute a major source of profit.

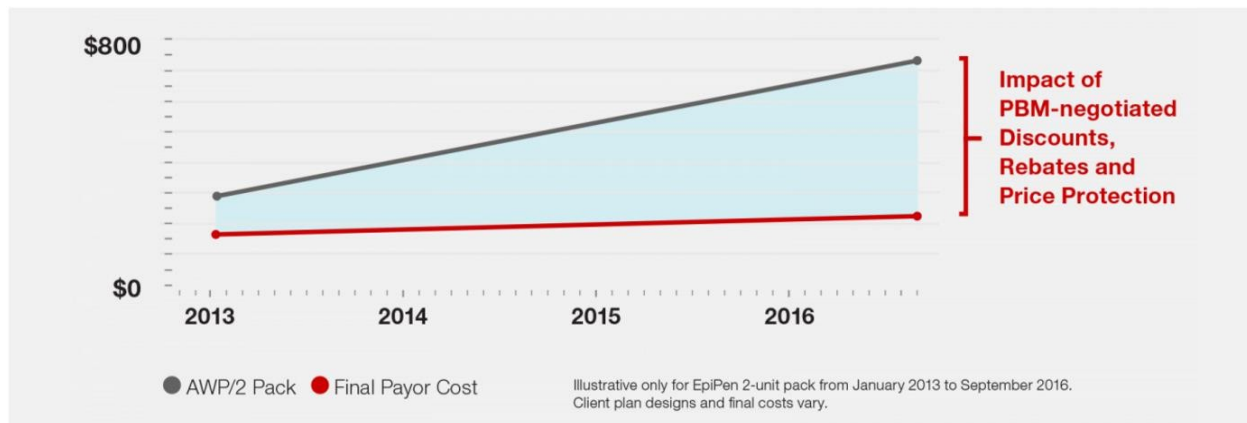
37. Rebates paid in exchange for delivering a certain number of filled prescriptions for a given drug are commonly known as “market share rebates” or “performance rebates.” PBMs may pass along an undisclosed portion of market share/performance rebates to their Third-Party Payer clients.

38. A third type of rebate, commonly known as a “price protection rebate,” is paid when a drug company increases a drug’s benchmark price beyond a certain agreed-upon threshold. These rebates protect PBMs from benchmark price increases, but do nothing to protect plan members who are subject to the benchmark price from those increases.

39. Rebates are most often calculated on a per-prescription or per-drug unit³ basis. This in turn requires PBMs to continuously compile rebate data and calculate rebate amounts for invoicing. PBMs generally invoice drug companies for rebate payments on a monthly or quarterly basis.

40. The nature and dollar amount of rebates paid to PBMs, as well as the amount passed on to their Third-Party Payer clients, is kept strictly secret. As a result of those rebates, PBMs and their clients ultimately pay prices for brand name drugs that are significantly lower than the benchmark prices to which Plaintiffs and the Class are subject.

41. For example, as CVS Health explains in an October 11, 2016 communication to its Third-Party Payer clients, “[w]hile EpiPen’s price has increased 150% over three years, we’ve been able to keep our clients’ cost growth to less than 10% per year.”⁴ CVS Health’s EpiPen chart illustrates this point:



³ A drug unit is a single unit of a given drug. For example, a single pill is a drug unit. In the case of EpiPen, a drug unit is a single EpiPen.

⁴ Available at: <http://insights.cvshealth.com/sites/default/files/cvs-health-insights-executive-briefing-epipen-what-you-need-to-know-october-2016.pdf>

42. CVS Health explains: “The chart above demonstrates the impact of PBM management on pricing for EpiPen over three years, including the negotiated discounts, rebates and price protection.” *Id.* It also shows the exploding rebates CVS Health negotiated with EpiPen’s maker Mylan from 2013-2016. Thus, while the price of EpiPen has increased much less for PBMs such as CVS Health and its Third-Party Payer clients, as shown by the red line in the chart, it has massively increased for members of the Class, who pay prices for EpiPen based on the exploding benchmark price, as shown by the gray line in the chart.

43. Similarly, in the face of increasing scrutiny into the benchmark price of EpiPen, Express Scripts has touted the use of rebates to reduce costs for its Third-Party Payer clients. For example, on February 7, 2017, in response to questions about the role of Express Scripts in the skyrocketing price of EpiPen, Express Scripts CEO Tim Wentworth told CBS News that, through rebates, “the unit price of drugs went up 2.5%,” which is “good news [] for our clients.” Notably, in October 2016, Express Scripts received subpoenas from the U.S. Attorney’s Office for the Southern District of New York and the District of Massachusetts regarding financial transactions with drug companies.

44. Prime has also promoted the use of drug company rebates to drive down Third-Party Payer. For example, on May 14, 2015, Prime issued a press release entitled “Managing medical-benefit drug spend is critical—and we can help,” which stated: “We leverage our relationships with [drug companies] to negotiate maximum rebates and drive down net costs.”

45. In an October 15, 2016 interview with *Modern Healthcare* magazine, Mark Thierer, CEO of Optum, stated that Optum negotiates with drug companies and “contract[s] for the protection of our clients. That’s what they pay us to do.” He further stated that Optum acts “as a guardian” so Third-Party Payer clients don’t see the full impact of a drug price increase. On December 14, 2016, Optum issued a press release entitled “Fall, 2016: OptumRx Trend Update,” which touted savings to clients through the use of “rebate aggregation.” That same day, Optum issued a press release entitled “Should all PBM contracts be value based?” that defined a rebate contract as one “where discounts are paid by [drug companies] for preferred placement on PDLs (Prescription Drug Lists),” *i.e.*, formularies.

46. While PBMs boast that aggressive rebates yield significant savings for their Third-Party Payers clients, industry experts have found otherwise. For example, Linda Cahn of Pharmacy Benefit Consultants, a well-known PBM consultant to Third-Party Payers, noted in a press release that PBMs often play a “Rebate Re-Labeling Game” in their client contracts, wherein PBMs define drug company rebates in narrow terms in order to remit only a fraction of those amounts to Third-Party Payers.⁵ The Burchfield Group, a PBM auditing company based in Saint Paul, Minnesota, has echoed this concern in various press releases.⁶

⁵ Available at: <http://nationalprescriptioncoveragecoalition.com/message-from-mylan-its-time-for-every-health-plan-to-address-rebate-issues/>.

⁶ Available at: [http://www.burchfieldgroup.com/pharmacy-benefit-blog/bid/203233/Receive-full-value-from-your-PBM-rebates](http://www.burchfieldgroup.com/pharmacy-benefit-blog/bid/203233/Receive-full-value-from-your-PBM-rebates;); <http://www.burchfieldgroup.com/pharmacy-benefit-blog/getting-your-fair-share-5-tips-for-optimizing-pbm-rebates>.

47. Notably, Third-Party Payers are often none the wiser because they are unaware of the specific terms of the rebate agreements between PBMs and drug companies. As noted by Steve Pociak of the American Consumer Institute:

[O]nly a PBM has a complete understanding of the prices and costs flowing between the various players involved in prescription plans. This unique insight comes from a PBM's involvement in administering prescription plans for sponsors (and their employees and beneficiaries), and from the PBM acting as middleman in a series of opaque transactions involving sponsors, beneficiaries, pharmacies and [drug companies]. These interactions among various parties create an environment for conflicts that drive PBMs to work for their self-interests, unbeknownst to the sponsor or beneficiary.⁷

48. In mid-2016, thirty of the country's largest employers, including American Express, Macy's, and Coca-Cola formed an organization called the Health Transformation Alliance, whose goal is to break with "existing marketplace practices that are costly, wasteful, and inefficient, all of which have resulted in employees paying higher premiums, copayments, and deductibles every year." According to Barron's, "They'd do this by rewriting their pharmacy-benefit contracts to eliminate the undisclosed drug-price markups that supply much of the PBM industry's profits."⁸

i. Formulary Placements and Exclusions

49. PBMs create and/or manage their Third-Party Payer clients' formularies. Most formularies have multiple tiers of coverage. The tier in which a drug is placed determines the amount of prescription drug benefits the Third-Party Payer provides for

⁷ Available at: <http://www.theamericanconsumer.org/wp-content/uploads/2017/03/ACI-PBM-CG-Final.pdf>.

⁸ Available at: <http://www.barrons.com/articles/pharmacy-benefit-managers-under-fire-1469247082>.

the drug. As discussed below, plan members typically pay less out-of-pocket for drugs in preferred formulary tiers. If a drug is not listed on the formulary, most Third-Party Payers will not cover it at all.

50. Given that formularies are determinative of prescription drug benefits, PBMs successfully use formularies to steer plan members toward certain brands of drugs over others. PBM formularies favor certain brand drugs over others based on safety, efficacy, and cost (*i.e.*, the amount of rebates paid by the drug companies).

51. Over the last several years, PBMs have successfully extracted enormous rebates from brand name prescription drug companies, including Mylan, for two principal reasons. First, since 2007, PBMs began consolidating into what are now four major entities—Express Scripts, CVS Health, Optum, and Prime—that administer prescription drug benefits for more than 200 million Americans. Consequently, for drug companies, including Mylan, the formularies established by Express Scripts, CVS Health, Optum, and Prime are the exclusive gateway to the vast majority of the prescription drug market.

52. Second, these PBMs operate what are known as closed formularies. Up until approximately 2007, PBMs devised and managed what are known as open formularies—formularies that offer prescription drug benefits for virtually all available FDA-approved drugs to varying degrees. Consequently, in an open formulary scheme, drug companies compete to have their drugs placed into the most favorable tier possible.

53. Closed formularies similarly provide tiered benefits, but also restrict the overall number of drugs covered, causing drug companies to compete not only for favorable tier placement, but simply to have their drugs appear on the PBM formularies

in the first place, and thus to have access to significant swathes of the American pharmaceutical market.

54. In addition to the increase in percentage of closed formularies, PBMs have most recently increased the number of drugs excluded from their standard formularies year-over-year. Indeed, while formulary exclusions of brand name drugs have always existed in narrowly-defined circumstances,⁹ as *Managed Care Magazine* stated in its April 2015 issue, “[o]ver the past 18 months, the use of formulary exclusions has changed from being a targeted tactic to a commonly used weapon.” For 2017, CVS Health excluded 154 drugs from its standard formulary, 124 in 2016, 95 in 2015, 72 in 2014, and 34 in 2012; Express Scripts excluded 85 drugs from its 2017 standard formulary, 87 in 2016, 66 in 2015, and 48 in 2014; and OptumRx and Prime likewise expanded exclusions in 2016.

55. Formulary exclusions generally occur where multiple drugs are deemed therapeutically interchangeable, as has been the case at certain times with epinephrine auto-injectors.

56. The threat of formulary exclusion is a major factor in rebate negotiations between the four major PBMs and drug companies. Indeed, in April 2015, Steve Miller, Express Scripts’ Chief Medical Officer, told *Managed Care Magazine* that formulary exclusions “demonstrate that PBMs move market share.” Miller further touted that drug companies “[are] now convinced . . . that we [can] actually deliver market share when we

⁹ For example, drugs that are found to be unsafe have been excluded from formularies. In addition, certain highly specialized prescription drug plans, such as those that cover exclusively generic drugs, will inevitably exclude a significant number of drugs.

[are] motivated to. So we went to the companies, and we told them, ‘We’re going to be pitting you all against each other. Who is going to give us the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We’ll exclude the other products.’”

57. As PBMs have extracted larger and larger rebates from drug companies over the last several years, their revenues have soared. Between 2010 and 2016, Express Scripts’ revenue jumped from approximately \$45 billion to north of \$100 billion. Optum’s revenue increased from roughly \$32 billion in 2014 to more than \$60 billion in 2016. CVS Health’s Pharmacy Services Segment, which encompasses CVS Health’s PBM, saw revenues climb from \$76 billion in 2013 to more than \$100 billion in 2015. Prime’s revenues rose from \$1.8 billion in 2012 to \$4.36 billion in 2015.

C. Drug Costs for Plan Members with Prescription Drug Benefits

58. In addition to monthly or annual premiums, health plan members with prescription drug benefits often have to pay a certain amount out-of-pocket when filling a prescription at a pharmacy. That amount is determined by the terms of the members’ health insurance plan. Out-of-pocket costs dictated by health insurance plans come in three forms: deductibles, coinsurance requirements, and/or copayment requirements.

59. *Deductibles.* The term “deductible” refers to a fixed dollar amount that a health plan member must pay out-of-pocket annually for medical and/or prescription drug costs before the member’s plan will issue healthcare reimbursements, including for prescription drug purchases. For example, a given health plan might require its members to pay \$3,000 out-of-pocket before issuing reimbursements. ERISA health plan terms

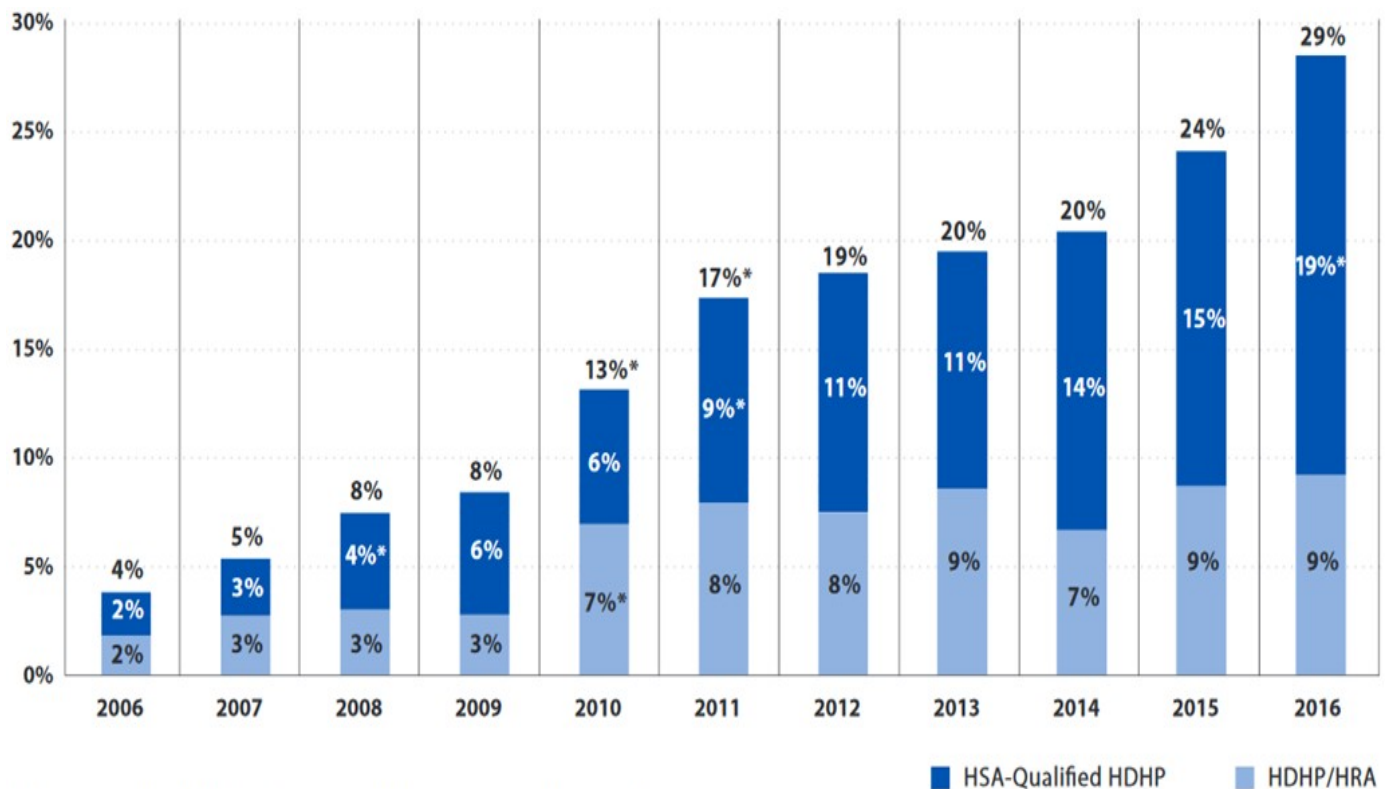
dictate that each year, before the plan member has paid the full deductible amount, the price that the insured pays for a given brand name drug is the full amount that the PBM reimburses the pharmacy for that drug. As previously discussed, this price falls somewhere between the drug's AWP and WAC.

60. Although most ERISA health plans have some form of a deductible, high-deductible health plans (HDHPs) have multi-thousand dollar annual deductibles.¹⁰ According to a January 5, 2016 report from the Kaiser Family Foundation and the Journal of the American Medical Association ("JAMA"), deductibles rose 67% between 2010 and 2015. The average annual deductible for an individual enrolled in a high-deductible plan is now between \$2,031 and \$2,295 for individuals and \$4,321 and \$4,364 for families.

61. Moreover, the percentage of covered workers enrolled in high-deductible health plans has increased from 13% in 2009 to 29% in 2016.

¹⁰ As of 2017, HDHPs are those with minimum annual deductibles of \$1,300 for individuals and \$2,600 for families. See <https://www.healthcare.gov/glossary/high-deductible-health-plan/>.

Figure 2: Percentage of Covered Workers Enrolled in High-Deductible Health Plans from 2006-2016



*Estimate is statistically different from estimate for the previous year shown ($p < .05$).

NOTE: Covered Workers enrolled in an HDHP/SO are enrolled in either an HDHP/HRA or a HSA-Qualified HDHP. For more information see the Survey Methodology Section. The percentages of covered workers enrolled in an HDHP/SO may not equal the sum of HDHP/HRA and HSA-Qualified HDHP enrollment estimates due to rounding.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

62. Rising drug benchmark prices (AWP and WAC) are particularly harmful to those in these high-deductible plans, who often have trouble affording prescription drugs, and are even forced to forego purchasing needed prescription drugs, due to high annual out-of-pocket costs.¹¹

¹¹ Even where plan members have minimal deductibles or no deductible at all, some Third-Party Payers place limits on the amount of auto-injectors covered each year, so plan members who have multiple anaphylactic episodes per year may end up spending higher out-of-pocket amounts because they are required to purchase additional EpiPens without coverage.

63. *Coinsurance and Copayments.* Most ERISA health insurance plans require plan members to make copayments¹² or coinsurance payments¹³ for medical care and prescription drugs. A copayment is a fixed dollar amount that plan members must pay at the time they receive medical care or prescription drugs. In the case of prescription drugs, plan members pay copayments to the pharmacy. Copayment amounts vary depending on the drug. Drugs placed by the PBMs in preferred formulary tiers require lower copayments, while drugs placed in less favored tiers require greater copayments.

64. For example, a PBM formulary with three copayment tiers could have copayments of \$25/\$50/\$75, in which case an insured would pay \$25 to fill a prescription for a first-tier drug, \$50 for a second-tier drug, and \$75 for a third-tier drug.

65. Coinsurance is similar to copayments. However, instead of paying a fixed amount for a particular service, plan members whose ERISA health insurance plans have coinsurance requirements pay a fixed *percentage* of the cost of the healthcare service provided. For a prescription drug, this means paying to the pharmacy a percentage of the amount that the PBM reimburses the pharmacy for the drug, which, as previously discussed, falls somewhere between the drug's AWP and WAC. This percentage varies depending on the drug, with lower coinsurance rates for preferred drug tiers, and higher coinsurance rates for disfavored drug tiers.

66. For those plan members whose ERISA health plans have three or more tiers of cost sharing for prescription drugs, average coinsurance rates are 17% for first-tier

¹² Copayments are also known as “copays.”

¹³ Coinsurance payments are also known as “percentage-based copayments” or “percentage-based copays.”

drugs, 25% for second-tier drugs, 37% for third-tier drugs, and 29% for fourth-tier drugs.¹⁴ ERISA health insurance plans generally classify brand name drugs, including EpiPen, as second or third-tier drugs on their formularies. As a result, coinsurance payments for brand name drugs can be a heavy financial burden. With an EpiPen benchmark price of \$600, a plan member without a deductible, or whose deductible has been satisfied, would pay, under average coinsurance rates, \$150 if EpiPen were classified as a second-tier drug and \$222 if EpiPen were classified as a third-tier drug, up from \$52 or \$77 in 2012 when the benchmark price of EpiPen was \$208.

67. For those plan members whose ERISA health insurance plans have annual deductibles, copayments and coinsurance obligations begin after plan members exhaust their deductibles. Plans without a deductible require copayments or coinsurance contributions for every prescription drug purchase.

68. This complex price system leads to members of the Class paying drastically higher prices for EpiPen than their Third-Party Payers. If a plan member is responsible for all of her drug costs before she hits her deductible, she must pay the pharmacy reimbursement price—which is tied to the benchmark price—until she meets her deductible; if she has a coinsurance requirement, she pays for a percentage of the drug's benchmark price. In contrast, as previously discussed, Third-Party Payers receive discounts off the drug companies' benchmark prices through their PBMs. In other words,

¹⁴ These figures come from a 2016 Kaiser Family Foundation study of employer health benefits, which is available at: <http://kff.org/report-section/ehbs-2016-section-nine-prescription-drug-benefits/>.

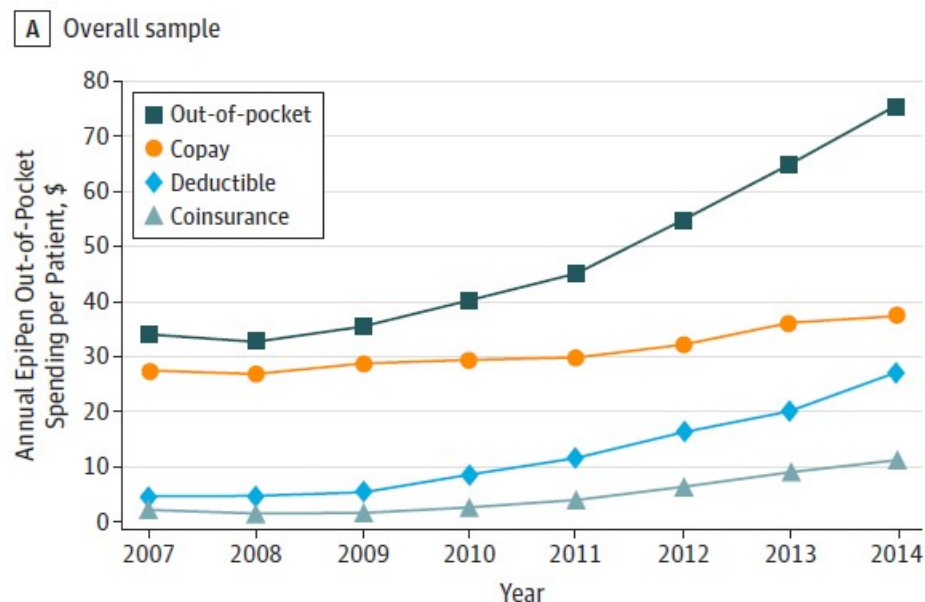
a Third-Party Payer's payment for EpiPen is based on a lower price than the plan member's payment.

69. An example helps illustrate this structure. A woman who has a child with a peanut allergy needs to purchase a two-pack of EpiPens.¹⁵ She goes to her local retail pharmacy where the pharmacist tells her the price is \$600. She has health insurance through her employer, and her insurance plan requires her to pay a \$2,000 deductible and then 30% coinsurance after she has hit her deductible. If she has not yet reached her \$2,000 deductible, she pays \$600 for the two-pack of EpiPens. If she has reached her deductible by having already paid \$2,000 in health care costs, she pays \$180 to the pharmacy (30% of \$600).

¹⁵ Prescription EpiPens dispensed to individuals are only available in two-packs.

70. A March 27, 2017 Research Letter published by the Journal of the American Medical Association (JAMA) (the “JAMA Research Letter”) shows that, since Mylan acquired the rights to market and distribute EpiPen in 2007, consumers have faced massive growth in out-of-pocket costs—including copayments, coinsurance payments, and deductible payments. The chart below was taken from the JAMA Research Letter:

Figure. Trends in Annual EpiPen Out-of-Pocket Spending per Patient



71. The JAMA Research Letter concluded: “Among commercially insured patients who use EpiPen, annual EpiPen out-of-pocket spending more than doubled between 2007 and 2014. Simultaneously, the annual rate of EpiPen prescription fills barely increased, suggesting that the increased financial burden on patients was not driven by higher use.”

72. In addition, according to the JAMA Research Letter, the percentage of commercially insured EpiPen patients with at least \$100 in annual out-of-pocket spending for EpiPen has increased between 2007 and 2014, from 3.9% to 18.0%, an increase of 365.6%. The percentage of EpiPen patients with at least \$250 in annual out-of-pocket spending has increased during those years from 0.1% to 7.4%, an increase of 5631.7%. Among the sampled population of people who receive private health insurance through more than 100 employers nationwide (which grew 70.9% between 2007 and 2014, to more than 25 million people), coinsurance payments for EpiPen increased 1531.6% and deductible payments increased 1612.0%, disproportionately higher than the increase in total EpiPen spending of 974.7%.

73. PBMs have acknowledged that EpiPen users face increasing out-of-pocket spending under the health plans whose benefits they administer. In an October 7, 2017 *Wall Street Journal* article about the significant out-of-pocket costs for EpiPen and insulin users due to high benchmark prices, Steve Miller of Express Scripts admitted that “certain patients get caught in the middle of this, and we have got to figure out how to put guard rails around that.”¹⁶

74. Similarly, in a September 2, 2016 article in *Pharmacy Practice News* regarding increasing EpiPen benchmark prices, David Lassen, Chief Clinical Officer of

¹⁶ Available at: <https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764>.

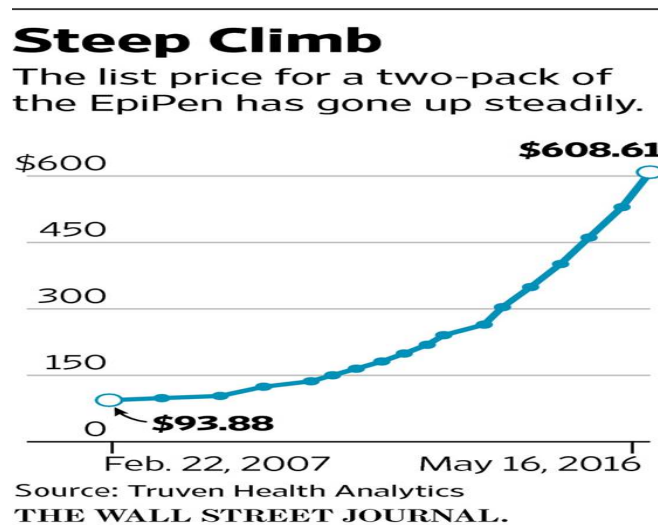
Prime, noted the increasing number of “high-deductible plans where the member would pay out of pocket the full cost up to a deductible amount.”¹⁷

75. The aforementioned CVS Health October 11, 2016 press release regarding increasing EpiPen benchmark prices and rebates noted that “copays have risen for many consumers over the last several years,” and that “members of consumer-driven or high deductible plans can also face large payment, which can pose a real deterrent when filling the prescription.”

D. Epinephrine Auto-Injectors

76. EpiPen is an auto-injector, a device designed to allow a user or parent to easily administer the appropriate dosage of epinephrine in the event of an anaphylactic episode. While EpiPen has been on the market since 1988, Mylan did not develop the product. Instead, it acquired the rights to market and distribute EpiPen when, in 2007, Mylan acquired Merck KGaA, Merck’s generic pharmaceutical business, which owned those rights at the time. When Mylan acquired the right to market and sell EpiPen, in 2007, the benchmark price for a two-pack of the drug was less than \$100. By 2016, the benchmark price for the EpiPen had skyrocketed to more than \$600.

¹⁷ Available at: <http://www.pharmacypracticenews.com/Policy/Article/09-16/Prescribers-Payers-Respond-to-Epi-Pen-Price-Hikes/37832/ses=ogst?enl=true>.



77. Over the last several years, EpiPen has at times competed with two other epinephrine auto-injectors: Adrenaclick and Auvi-Q. Auvi-Q, a talking epinephrine injector, was released by Sanofi-Aventis, U.S. LLC (“Sanofi”), in 2013. It was pulled from the market in October 2015 in a voluntary recall over concerns the product might deliver inaccurate doses or fail to deliver the drug.

78. Adrenaclick, since its approval by the FDA in 2009, has faced a series of problems as well, including struggles to keep up with demand and concerns over instructions that differ somewhat from those for EpiPen. In 2013, after a period when Adrenaclick was off the market, its owner at the time, Amedra Pharmaceuticals, made the tactical decision to stop competing directly with the EpiPen and instead created an identical, but generic, version of Adrenaclick. However, Adrenaclick has continued to struggle to gain traction.

E. Increases in EpiPen Benchmark Prices Are Caused by Increases in PBM Rebates

79. Defendant PBMs have the responsibility and authority to negotiate lower prices for EpiPen on behalf of the ERISA health insurance plans and their plan members whose prescription drug benefits Defendant PBMs administer. They have failed to do so. Instead, the actions of Defendant PBMs have led to *increased* prices combined with higher rebates. The result is that the PBMs benefit financially, as they keep portions of the increased rebates as profit, to the direct detriment of ERISA plan members who are adversely impacted through dramatically higher out-of-pocket costs. In particular, while the PBMs have demanded higher and higher rebates, Mylan has been forced to keep raising benchmark prices for EpiPen. The result is higher costs for certain ERISA plan members, the Class members here who bear the brunt of these enormous EpiPen price increases.

80. PBMs benefit materially as a result of Mylan's combination of high benchmark prices and high rebates for EpiPen, which has had a direct impact on how Mylan's EpiPen is treated in the applicable formularies. In 2014, Express Scripts excluded Auvi-Q from its formulary, while EpiPen remained. Express Scripts defended the exclusion by stating: "In 2014 and 2015, we leveraged the competition between EpiPen and Auvi-Q to earn additional discounts for our clients." By 2015, Auvi-Q had learned its lesson, and likewise paid Express Scripts significant rebates in order to be restored to its formulary; however, Auvi-Q was recalled by Sanofi in late 2015.

81. Similarly, since at least 2015, in its standard formulary, CVS Health (formerly Caremark) has not covered EpiPen competitor Adrenaclick. CVS Health currently lists EpiPen as the formulary option for an epinephrine auto-injector and informs plan participants that if they use Adrenaclick, they “may be required to pay the full cost” and that they should ask their doctor to choose the “brand formulary option[] listed below,” meaning EpiPen. Since at least 2015, EpiPen was the brand on Optum’s standard formulary prescription drug lists, with Auvi-Q and Adrenaclick excluded. Prime’s main formularies, including Generics Plus and PrimeChoice, also listed EpiPen at the exclusion of Auvi-Q and Adrenaclick.

82. On April 24, 2017, EpiPen competitor Auvi-Q’s manufacturer, Sanofi sued Mylan for antitrust violations related to EpiPen, claiming that PBMs and Third-Party Payers gave EpiPen exclusive formulary coverage in exchange for “new and unprecedented rebates” from Mylan. *Sanofi-Aventis U.S. LLC v. Mylan Inc. and Mylan Specialty, L.P.*, No. 3:17-cv-02763, Complaint, at 3 (D.N.J. Apr. 24, 2017).

83. The ever-increasing rebates for EpiPen are also visible from a November 4, 2016 study issued by Argus Health. The study estimates (in pink below) how much Mylan pays in rebates to PBMs and health insurers.¹⁸ As shown in the chart below, EpiPen’s benchmark price increased from \$378 in 2014 to \$600 in 2016, an increase of more than 158%, while EpiPen’s post-rebate price increased less than 6%, from \$294 to \$311.

¹⁸ See AJ Ally, *The EpiPen Price Increase: A Deeper Look at a Complicated Story*, Argus Health, available at: <https://argus-health.com/2016/11/the-epipen-price-increase-a-deeper-look-at-a-complicated-story/>.



WAC = WHOLESALE ACQUISITION COST. ILLUSTRATIVE REBATE ANALYSIS FOR A GIVEN THREE-YEAR PERIOD

84. What the above chart shows is that the primary cause of the immense increase in the price of the EpiPen is the skyrocketing rebates being paid to Defendant PBMs and that the PBM rebates are by far the largest component of EpiPen's price increases. Defendant PBMs, not Mylan itself, are the primary beneficiaries of EpiPen price increases.

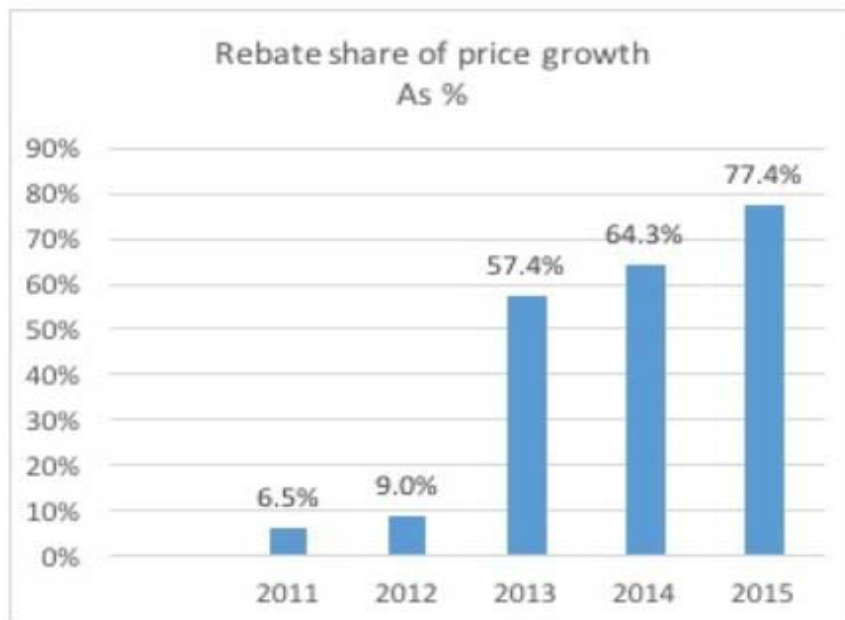
85. Mylan has confirmed paying exorbitant rebates to PBMs for EpiPen. In September 2016, Mylan's CEO, Heather Bresch, testified before the U.S. House of Representatives Committee on Oversight and Government Reform:

I know there is considerable concern and skepticism about the pricing of EpiPen Auto-Injectors. I think many people incorrectly assume we make \$600 off each EpiPen. This is simply not true.

In the complicated world of pharmaceutical pricing, there is something known as Wholesale Acquisition Cost or WAC. The WAC for a 2 unit pack of EpiPen Auto-Injectors is \$608. After rebates and various fees, Mylan actually receives \$274.

i. Recent Data Confirms a Strong Relationship between Greater PBM Rebates and Increasing Benchmark Prices

86. PBMs profit directly from, and are incentivized to, generate benchmark price inflation. As previously discussed, rebates are negotiated as a percentage of a drug's benchmark price. Thus, as benchmark prices increase, so do PBM profits. Indeed, as shown in the graph below,¹⁹ from 2011 - 2015, PBM profit margins between benchmark or list prices and post-rebate net prices have soared from 6.5% to an astounding 77.4%. In 2016, these margins increased to 79%.²⁰



87. The study further found that PBM rebates accounted for 71% of the total increase in spending for brand name drugs between 2014 and 2015.

¹⁹ Available at: <http://drugwonks.com/blog/most-of-the-increase-in-drug-spending-pocketed-by-pbms-and-insurers>.

²⁰ See <http://drugwonks.com/blog/reduce-drug-prices-by-cutting-out-pbm-rebates>.

88. In addition, according to an April 2016 study conducted by the IMS Institute for Healthcare Informatics, benchmark prices climbed from 2013 to 2016 between 11% and 14% per year, while prices excluding rebates grew between 2% and 5% per year.²¹



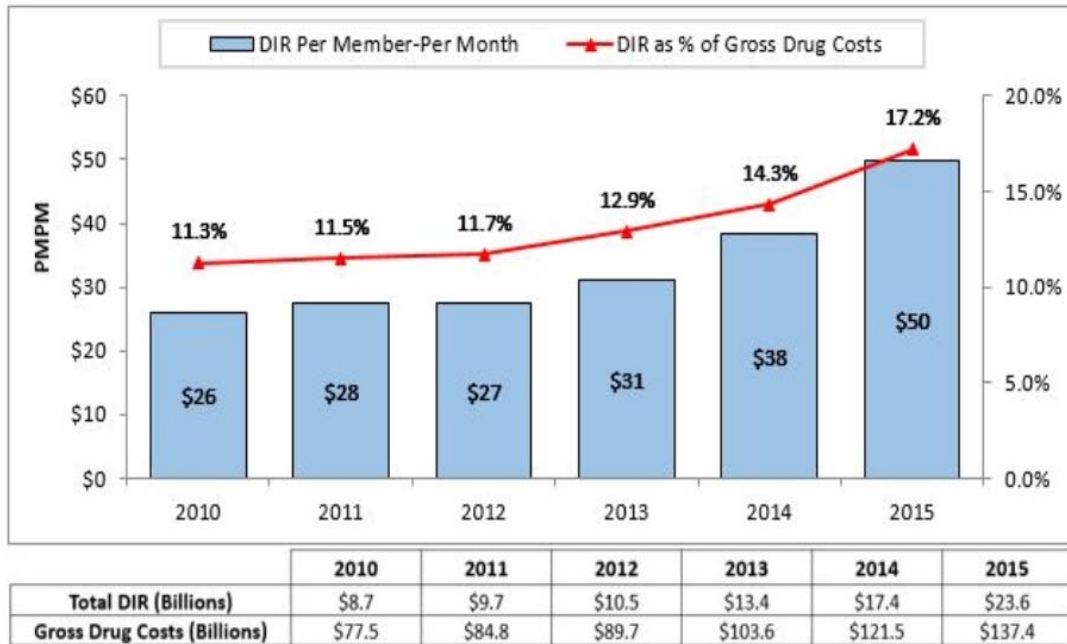
Source: IMS, Express Scripts

²¹ Available at: <https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf>

89. Similarly, in a January 19, 2017 report,²² the Centers for Medicare and Medicaid Services (“CMS”) observed “a notable growth in” Direct and Indirect Remuneration (“DIR”) compensation, which is largely made up of rebates from drug companies to PBMs and Medicare Part D prescription drug plan sponsors.²³ The report found a “growing disparity between gross [Medicare] Part D drug costs, calculated based on costs of drugs at the point-of-sale, and net Part D drug costs, which account for all DIR.” Like the aforementioned IMS studies, the CMS report states that “[g]ross drug cost and DIR have grown most dramatically since 2013.”

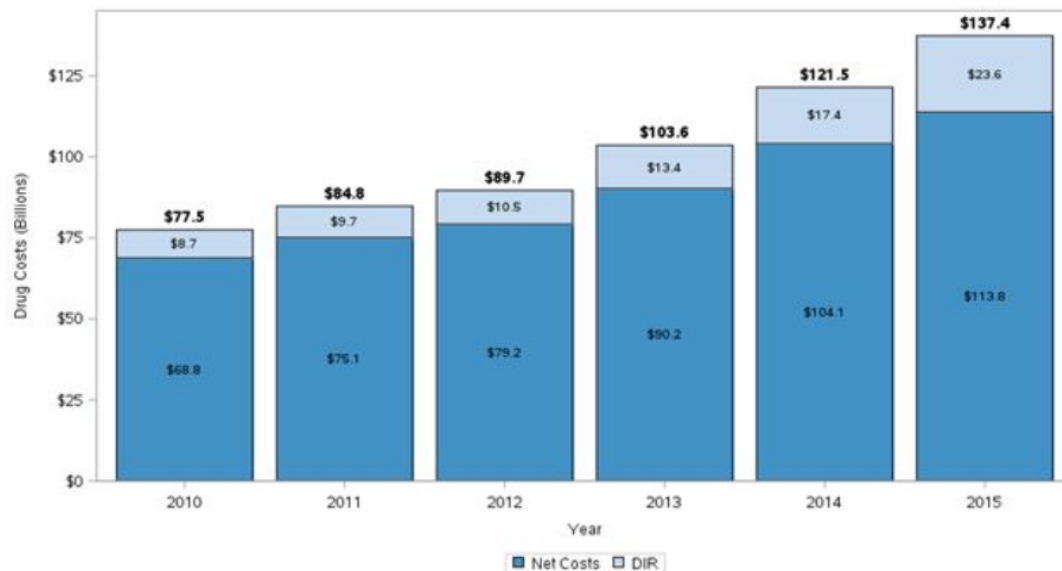
²² Available at: <https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html>.

²³ PBMs negotiate 2017-06-02 rebates from drug companies on behalf of Medicare Part D prescription drug plan sponsors. However, instead of the PBMs keeping a portion of those rebates, federal regulations require the PBMs to pass 100% of those rebates back to Medicare.



Source: Analysis of DIR and enrollment data from the 2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds (CY 2016 Medicare Trustee's Report) and cost data from PDE records.

Figure 2 – Net Drug Costs



Source: Analysis of DIR data from the CY 2016 Medicare Trustee's Report and cost data from PDE records.

F. PBM Rebates Increase Out-of-Pocket Expenses for Plan Members Who Fill EpiPen Prescriptions under Deductibles and Coinsurance Provisions

90. Given that (a) PBM rebates increase benchmark prices of EpiPen, and (b) deductible and coinsurance payments are tied to benchmark prices, PBM rebates for EpiPen increase out-of-pocket expenses for Class members, plan members who fill their EpiPen prescriptions under annual deductibles and coinsurance provisions.

91. The November 4, 2016 Argus Health study (*see* ¶ 83) demonstrates the remarkable correlation between rebates paid to PBMs and increasing EpiPen benchmark prices.

92. Likewise, the January 19, 2017 CMS report (*see* ¶ 89) shows a strong correlation between DIR (largely PBM rebates) and point-of-sale drug costs (based on benchmark prices, also referred to as list prices). The CMS report further states that DIR “does not reduce the cost of drugs for beneficiaries at the point-of-sale,” and that “[h]igher point-of-sale prices generally result in higher beneficiary cost-sharing obligations as cost-sharing is often assessed as a percentage of the list price.”

93. Defendant PBMs shift benchmark price increases onto Class members through the deductible and coinsurance provisions in their health plans. In other words, as PBMs cause—and profit from—EpiPen benchmark price inflation through solicitation and receipt of larger and larger rebates from Mylan, they turn around and administer benefits to Class members who purchase EpiPen at those inflated prices. And all the while, PBMs and their clients continue to expand deductible and coinsurance

requirements, thereby subjecting Class members to inflated benchmark prices on an ever-increasing basis.

94. Indeed, Mylan CEO Heather Bresch acknowledged this during a CNBC interview:

The patient is paying twice. . . . They're paying full retail price at the counter, and they're paying higher premiums on their insurance. It was never intended that a consumer, that the patients, would be paying list price, never. The system wasn't built for that.²⁴

95. Mylan has attempted to blunt the exposure of ERISA plan members to benchmark prices through its Patient Assistance Program (“PAP”) and My EpiPen Savings Card program. However, Mylan admits that these programs “did not keep pace with the evolving healthcare system, and, as a result, some patients are facing out-of-pocket costs.” The increasing number of patients with high-deductible healthcare plans and coinsurance obligations, together with the rise in deductible amounts and coinsurance percentages, has made the pain associated with the EpiPen price hikes particularly acute. Although epinephrine has been available for over a century and costs very little to produce, PBM profits have put EpiPen out of reach for many consumers.

96. Moreover, industry experts question whether Mylan could even lower benchmark prices to the benefit of plan members. Ronny Gal, a senior analyst at Sanford C. Bernstein & Co., told *Drug Benefit News* that because PBMs and Third-Party Payers determine what plan members pay for a drug, “rolling back price increases . . . would not necessarily help consumers much,” because “[t]o reduce prices, Mylan would have to

²⁴ Available at: <http://www.cnbc.com/2016/08/25/mylan-expands-epipen-cost-cutting-programs-after-charges-of-price-gouging.html/>

renegotiate increases, discounts and rebates to the payors.” Likewise, Elan Rubenstein, principal at EB Rubenstein Associates, explained: “[A] rebate is negotiated with each . . . PBM based on leverage and reciprocal value. A [drug company’s] lowering of list price is an across-the-board action, so it does not require reciprocity on the part of the . . . PBM, which will likely still want a rebate based on perceived leverage even after list price is lowered.”

97. Unable to afford EpiPens, many patients are now facing grave risks. They have started carrying expired EpiPens, or manually-filled syringes of epinephrine, even when they lack the medical training necessary to properly administer an injection.

98. Congress has started to acknowledge the role of PBMs and Third-Party Payers in driving up prescription drug prices for their plan members. On March 15, 2017, Senator Ron Wyden of Oregon introduced the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act, which would require PBMs to disclose the rebates they receive from drug companies.

99. U.S. Representative Earl L. Carter of Georgia recently discussed the role of PBMs in driving up the price of EpiPen on the floor of the House of Representatives. Rep. Carter, a pharmacist and the owner of a pharmacy, recently recalled the testimony of Heather Bresch, Mylan’s CEO:

It was really interesting because, during the time that we were asking questions of the CEO, she mentioned, well, when it leaves us, it is this price right here—I am just going to use round figures—it is \$150. By the time it gets to the pharmacist and by the time it is dispensed to the patient, it is \$600.

I asked her: What is that difference there? Where is that coming from?

I don't know.

I don't know either.

Now, there is the beginning and the end. The beginning is the pharmaceutical [company]. She doesn't know. The end is me, the dispensing pharmacist, and I don't know.

That is what I'm referring to when I talk about the man behind the curtain. That is where the PBMs come in.

Now, they will tell you: Well, we are taking that money, and we are giving it back to the companies, to the insurance.

Well, if they are, and they're not keeping any of it, then why are their profits going up so much? Why have their profits gone up over 600 percent? It's because they're keeping it. They're keeping it, and they're adding no value whatsoever to the system.

163 Cong. Rec. H1453 (daily ed. Mar. 1, 2017) (statement of Rep. Carter).

G. Plaintiffs' EpiPen Purchases

100. Defendants' solicitation and receipt of rebates from Mylan regarding EpiPen caused Plaintiffs and the Class to purchase EpiPen at inflated prices under the terms of their ERISA health plans. For example, on November 3, 2015, the Kleins filled a prescription for an EpiPen Jr. two-pack for their six-year-old son at their local pharmacy. Because they had yet to satisfy the \$5,000 annual deductible under their ERISA-governed health insurance plan, they were subject to the full benchmark-related price of \$468.93, pursuant to the terms of their plan. Using a pharmacy coupon, they reduced their out-of-pocket cost to \$368.93.

101. On November 18, 2015, the Kleins filled another prescription for an EpiPen two-pack for their son at their local pharmacy. Again, they were subject to the

benchmark-related price of \$468.93 under the terms of their ERISA health insurance plan because they had yet to satisfy the plan's \$5,000 annual deductible. Using a pharmacy coupon, they reduced their out-of-pocket cost to \$368.93.

102. On January 6, 2017, the Kleins filled two more prescriptions, each for an EpiPen two-pack, for their son at their local pharmacy. This time, they were subject to the benchmark-related price of \$1,227.95 (nearly \$614 for each two-pack) under the terms of their ERISA health insurance plan because they had yet to satisfy the plan's \$5,200 annual deductible. Using a pharmacy coupon, they reduced their out-of-pocket cost to \$627.95.

103. On or about April 18, 2013, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price under the terms of her ERISA health insurance plan. She paid \$258.65 for the prescription at a pharmacy in Minneapolis, Minnesota. Ms. Weaver's PBM for that purchase was Express Scripts.

104. On or about May 24, 2014, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price under the terms of her ERISA health insurance plan. She paid \$274.72 for the prescription at a pharmacy in Minneapolis, Minnesota. Ms. Weaver's PBM for that purchase was Express Scripts.

105. On or about April 16, 2015, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price under the terms of her ERISA health insurance plan. She paid \$232.89 for the prescription at a pharmacy in Minneapolis, Minnesota. Ms. Weaver's PBM for that purchase was CVS Health.

106. On or about June 18, 2015, Ms. Weaver filled an EpiPen prescription and

was subject to a benchmark-related price under the terms of her ERISA health insurance plan. She paid \$265.00 for the prescription at a pharmacy in Bemidji, Minnesota. Ms. Weaver's PBM for that purchase was CVS Health.

107. On or about April 20, 2017, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price under the terms of her ERISA health insurance plan. She paid \$317.23 for the prescription at a pharmacy in Minneapolis, Minnesota. Ms. Weaver's PBM for that purchase was Express Scripts.

108. Mrs. Paschalidis has filled EpiPen prescriptions under her ERISA health insurance plan. In doing so, she has been subject to benchmark-related prices under the terms of that plan. She has never paid the full benchmark price, however, because she is unable to afford it. Instead, she fills her EpiPen prescriptions using a drug company or pharmacy coupon that reduces her out-of-pocket cost to an amount between approximately \$150 and \$250.

V. CLASS ALLEGATIONS

109. Plaintiffs bring this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a), as well as 23(b)(1), 23(b)(2), and 23(b)(3), as representatives of the following Class:

All persons residing in the United States and its territories who are participants in, or beneficiaries of, health insurance plans governed by ERISA, for which Defendants administered pharmacy benefits, and who paid any portion of the purchase price for EpiPen or EpiPen Jr. calculated by reference to a benchmark price, including but not limited to WAC (Wholesale Acquisition Cost) or AWP (Average Wholesale Price), as required by the terms of their health insurance and/or prescription drug benefit plans. The class begins on June 2, 2011 and continues through the present. Excluded from the class are

governmental entities; Defendants; any parent, subsidiary, or affiliate of Defendants; Defendants' officers, directors, and employees; and the immediate family members of Defendants' officers, directors, and employees.

Plaintiffs reserve the right to redefine the Class prior to certification.

110. Plaintiffs will seek Class certification, restitution, disgorgement of profits, and other available relief for fiduciary breaches and prohibited transactions occurring within the entire period allowable under ERISA § 413, 29 U.S.C. § 1113, including its fraud or concealment tolling provisions.

111. This action is brought, and may properly be maintained, as a Class action pursuant to Federal Rule of Civil Procedure 23. This action satisfies the numerosity, typicality, adequacy, predominance, and superiority requirements of those provisions. The members of the Class are readily ascertainable from records maintained by the Defendants and/or Third-Party Payers.

112. Numerosity. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiffs at this time, Plaintiffs believe that likely tens of thousands of individuals will be members of the Class and that those individuals are readily identifiable in Defendants' records. According to the Pharmaceutical Care Management Association, as of 2016, PBMs administer prescription drug benefits for 266 million Americans. The four largest PBMs—Express Scripts, CVS Health, Optum, and Prime—administer prescription drug benefits for more than 200 million Americans. Moreover, according to IMS Health, more than 3.6 million EpiPen prescriptions were

written in 2015. According to Mylan, nearly 70% of the prescriptions were for commercially insured patients.

113. Typicality. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and Class members all paid a portion of the purchase price for EpiPen calculated by reference to a benchmark price. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants—*i.e.*, as a result of Defendants' misconduct, breaches of their fiduciary duties, and/or in violation of ERISA, these purchasers paid artificially inflated prices for EpiPen.

114. Adequacy. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiffs are coincident with, and not antagonistic to, those of the other members of the Class. Plaintiffs have retained counsel that are competent and experienced in the prosecution of complex class action litigation, including ERISA litigation, and have particular experience with class action litigation involving health insurers. Plaintiffs' counsel will undertake to vigorously protect the interests of the Class.

115. Commonality. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members. The claims of all Class members originate from the same misconduct, breaches of fiduciary duties, and violations of ERISA perpetrated by Defendants.

116. Questions of law and fact common to Plaintiffs and the Class include:

- a. Whether Defendant PBMs are fiduciaries under ERISA;

- b.** Whether Defendant PBMs act as ERISA fiduciaries in soliciting, negotiating, and receiving rebates from Mylan regarding EpiPen;
- c.** Whether Defendant PBMs act as ERISA fiduciaries in administering health plan benefits for EpiPen to Class members based on a benchmark-related price;
- d.** Whether Defendant PBMs breached their fiduciary duties to Class members by soliciting, negotiating, and receiving rebates from Mylan regarding EpiPen that caused an increase in EpiPen's benchmark price;
- e.** Whether Defendant PBMs breached their fiduciary duties to Class members by administering health plan benefits for EpiPen to Class members based on a benchmark-related price;
- f.** Whether Defendant PBMs engaged in prohibited transactions;
- g.** Whether Class members are entitled to restitution, surcharge, an injunction, and/or other appropriate equitable relief; and
- h.** Whether the Defendant PBMs knowingly participated in and/or knew or had constructive knowledge of violations of ERISA, including breaches of fiduciary duty.

117. Under Rule 23(b)(3), class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

118. This action is also maintainable as a class action under Rule 23(b)(2)

because Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby making appropriate final injunctive, declaratory, or other appropriate equitable relief with respect to the Class as a whole.

119. With respect to Rule 23(b)(1)(B), the prosecution of separate actions by each plaintiff in the Class would create a risk of adjudications with respect to individual members of the Class that would, as a practical matter, be dispositive of the interests of the other members not parties to the actions, or substantially impair or impede their ability to protect their interests.

120. Finally, Class action status is also warranted under Rule 23(b)(1)(A) because prosecution of separate actions by the members of the Class would create a risk of establishing incompatible standards of conduct for Defendants.

121. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VI. CLAIMS FOR RELIEF

122. Section 502(a)(3) of ERISA authorizes individual participants and beneficiaries to bring suit “(A) to enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan.” 29 U.S.C. § 1132(a)(3). The remedies set forth in § 502(a)(3) include remedies for breaches of the fiduciary duties set forth in ERISA § 404, 29 U.S.C. § 1104, and for violation of the prohibited transaction rules set forth in ERISA § 406, 29 U.S.C. § 1106.

123. ERISA defines a fiduciary as any person who “exercises any discretionary authority or discretionary control respecting management of [a] plan or exercises any authority or control respecting management or disposition of its assets.” 29 U.S.C. § 1002(21)(A)(i), (iii).

124. Defendants acted as fiduciaries in administering prescription drug benefits and determining eligibility for benefits and benefit amounts for the Class.

125. Defendants acted as fiduciaries in engaging in rebate transactions regarding EpiPen in exchange for placement on Defendants’ and their clients’ formularies and/or in exchange for a certain number of EpiPen prescriptions—*i.e.*, access to prescription drug benefits. Consequently, in engaging in such transactions, Defendants exercised discretionary authority or control regarding the management and/or disposition of plan assets.

126. Defendants acted as fiduciaries while engaging in rebate transactions regarding EpiPen because those transactions directly affect the benchmark price of EpiPen, and, in turn, Defendants’ administration of prescription drug benefits under deductible and coinsurance provisions in the Class members’ health plans. Consequently, in engaging in such transactions, Defendants exercised discretionary authority or control regarding the management and/or disposition of plan assets.

127. Defendants acted as fiduciaries in the administration of plan benefits regarding EpiPen because the rebate transactions in which they engaged regarding EpiPen directly affect the benchmark price of EpiPen, and, in turn, Defendants’

administration of prescription drug benefits under deductible and coinsurance provisions in the Class members' health plans.

A. Fiduciary Duties under ERISA

i. The Duty of Loyalty

128. Section 404(a)(1)(A) of ERISA, 29 U.S.C. §§ 1104(a)(1)(A), provides that a fiduciary shall discharge his duties with respect to a plan solely in the interest of the plan's participants and beneficiaries and for the exclusive purpose of providing benefits to participants and their beneficiaries. Defendants violated their duty to administer prescription drug benefits solely in the interests of Class members, ERISA health insurance plan participants and beneficiaries. Defendants caused EpiPen benchmark price increases through solicitation and receipt of increasing rebates from Mylan for EpiPen. Defendants kept a significant portion of those rebate amounts for themselves, in exchange for placement of EpiPen on Defendants' and their clients' formularies and/or delivering a certain market share or number of prescriptions. At the same time, Defendants administered prescription drug benefits for EpiPen based on the benchmark price or a percentage thereof, resulting in enormous increases in out-of-pocket costs borne by members of the Class.

129. ERISA also holds fiduciaries liable for the misconduct of co-fiduciaries. ERISA § 405(a), 29 U.S.C. § 1105(a). Co-fiduciary liability is an important part of ERISA's regulation of fiduciary responsibility. Because ERISA permits the fractionalization of fiduciary duties, there may be, as in this case, more than one ERISA fiduciary involved in a given issue. Defendants are liable for other fiduciaries'

misconduct as co-fiduciaries. Defendants are fiduciaries with respect to the ERISA health insurance plans at issue in this case and have participated in and enabled other fiduciaries' breaches under ERISA § 404. By engaging in rebate transactions regarding EpiPen on behalf of other fiduciaries that caused increases in EpiPen's benchmark price, while at the same time administering plan benefits for EpiPen to Class members on behalf of those fiduciaries, based on the benchmark price, Defendants participated in and enabled those fiduciaries' breach of their duty of loyalty to members of the Class.

ii. Duty to Avoid Conflicted Transactions

130. Section 406(b)(2) of ERISA, 29 U.S.C. § 1106(b)(2), strictly prohibits a fiduciary from engaging "in any transaction involving the plan on behalf of a party . . . whose interests are adverse to the interests of the plan or the interests of its participants or beneficiaries." Defendants violated their duty to avoid conflicted transactions by soliciting and receiving increasing rebates from Mylan for EpiPen, in exchange for placement of EpiPen on Defendants' formularies and/or delivering a certain market share or number of prescriptions, because doing so inflated the benchmark price of EpiPen. Defendants' conduct creates a conflict of interest between Defendants and the Class. Defendants' interests are to maximize rebates, a significant portion of which they keep for themselves, and which are determined by the benchmark price. A higher benchmark price for EpiPen increases their profits. Defendants' interests are adverse to Class member interests in minimizing deductible and coinsurance payments for EpiPen, which are also determined by the benchmark price.

131. Parties-in-interest can also be held liable for violations of Section 406 of

ERISA. As defined in Section 3(14)(A) of ERISA, a party in interest includes “any fiduciary (including, but not limited to, any administrator, officer, trustee, or custodian), counsel, or employee of such employee benefit plan,” or “a person providing services to such plan.” 29 U.S.C. § 1003(14)(A). Defendants have been parties-in-interest to the Class members’ ERISA health plans that they administer because each was a fiduciary of these Plans and/or was “a person providing services to” those plans. As parties in interest, Defendants are each liable for the prohibited transactions identified in this Complaint to which they were parties.

B. Non-Fiduciary Liability

132. Non-fiduciaries may be held liable for ERISA violations where they knowingly participate in and/or profit from a fiduciary’s breach of duty or a prohibited transaction. Accordingly, as to the ERISA claims asserted in this Complaint, even if Defendants are not found to have fiduciary status themselves, they must nevertheless restore unjust profits or funds and are subject to other appropriate equitable relief pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3). Defendants engaged in rebate transactions regarding EpiPen on behalf of ERISA plan fiduciaries with the knowledge that those transactions caused increases in EpiPen’s benchmark price. At the same time, Defendants knowingly administered prescription drug benefits for EpiPen to Class members on behalf of ERISA plan fiduciaries based on the benchmark price, with knowledge of the resulting increases in out-of-pocket costs borne by Class members. Defendants also knew that their interests in maximizing rebates for themselves and ERISA plan fiduciaries were adverse to Class member interests in minimizing

deductible and coinsurance payments for EpiPen, which are determined by the benchmark price.

FIRST CLAIM FOR RELIEF

ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3) for Breach of Fiduciary Duties under ERISA § 404(a)(1)(A), 29 U.S.C. § 1104(a)

133. Plaintiffs incorporate by reference each of the preceding paragraphs as though fully set forth herein.

134. Defendants are fiduciaries of the ERISA health insurance plans in which Plaintiffs and/or Class members are participants or beneficiaries because Defendants exercise discretionary authority and/or discretionary control over prescription drug benefits. As such, they owe fiduciary duties under ERISA to the Class members.

135. Defendants breached their duty of loyalty under ERISA § 404(a)(1)(A) because Defendants caused EpiPen benchmark price inflation through solicitation and receipt of increasing rebates from Mylan for EpiPen. Defendants kept a significant portion of these rebates as profit, while at the same time administering prescription drug benefits for EpiPen based on the benchmark price or a percentage thereof, resulting in enormous increases in out-of-pocket costs borne by members of the Class.

136. In so doing, Defendants failed to act solely in the interest of Plaintiffs and the Class, and instead acted in their own interests at the expense of Plaintiffs and the Class.

137. Defendants are also liable as co-fiduciaries under ERISA § 405(a), 29 U.S.C. § 1105(a), for knowingly participating in and enabling other fiduciaries' breaches of their duty to act solely in the interests of Plaintiffs and the Class.

138. To the extent that Defendants are not deemed fiduciaries, Defendants are

liable as non-fiduciaries to disgorge ill-gotten gains and/or provide other appropriate equitable relief, pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), because Defendants had actual or constructive knowledge of and participated in other fiduciaries' violations of ERISA.

139. Defendants' breaches of fiduciary duty caused direct injury and losses to Plaintiffs and the Class.

140. Plaintiffs and the Class seek appropriate equitable relief, along with such other and additional relief enumerated in the Prayer and/or as may be otherwise available.

SECOND CLAIM FOR RELIEF

ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3) for Prohibited Transactions under ERISA § 406(b)(2), 29 U.S.C. § 1106(b)(2)

141. Plaintiffs incorporate by reference each of the preceding paragraphs as though fully set forth herein.

142. Defendant PBMs engaged in prohibited transactions as fiduciaries. They violated ERISA § 406(b)(2) by soliciting and receiving increasing rebates from Mylan for EpiPen, thereby inflating the benchmark price of EpiPen. This creates a conflict of interest between Defendants and the Class because Defendants' interests in maximizing rebates to keep for themselves are adverse to Class member interests in minimizing out-of-pocket costs for EpiPen, which are based on the benchmark price.

143. To the extent that Defendants are not fiduciaries with regard to any of the prohibited transactions under ERISA § 406(b)(2) alleged above, Defendants are liable to disgorge ill-gotten gains and/or provide other equitable relief as to the transactions set

forth above, pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), because they were parties in interest with regard to each such transaction.

144. To the extent that Defendants are not fiduciaries or parties in interest, Defendants are liable as non-fiduciaries to disgorge ill-gotten gains and/or provide other appropriate equitable relief, pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), because Defendants had actual or constructive knowledge of, and participated in, fiduciaries' violations of ERISA.

145. Defendants' violations of ERISA § 406(b)(2) caused direct injury and losses to Plaintiffs and the Class.

146. Plaintiffs and the Class seek appropriate equitable relief, along with such other and additional relief enumerated in the Prayer and/or as may be otherwise available.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the Class, pray for relief as follows:

- a.** Certifying this action as a class action and appointing Plaintiffs and the counsel listed below to represent the Class;
- b.** Finding that Defendants violated their fiduciary duties to ERISA plan participants and beneficiaries and awarding Plaintiffs and the Class such relief as the Court deems proper;
- c.** Finding that Defendants engaged in prohibited transactions and awarding Plaintiffs and the Class such relief as the Court deems proper;
- d.** Awarding Plaintiffs and the Class equitable relief to the extent permitted by the above claims;

- e. Finding that Defendants are jointly and severally liable as fiduciaries and/or co-fiduciaries and/or non-fiduciaries;
- f. Awarding Plaintiffs' counsel attorneys' fees, litigation expenses, expert witness fees, and other costs pursuant to ERISA § 502(g)(1), 29 U.S.C. § 1132(g)(1), and/or the common fund doctrine; and
- g. Awarding such other and further relief as may be just and proper.

Dated: June 2, 2017

Respectfully submitted,

LOCKRIDGE GRINDAL NAUEN P.L.L.P.

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